Introduced by Assembly Member Vargas

February 22, 2005

An act to amend Section 109948.1 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1656, as introduced, Vargas. Automated external defibrillators. Existing law, the Sherman Food, Drug, and Cosmetic Law, requires the State Department of Health Services to regulate the manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act, and excludes an automated external defibrillator from the definition of a home medical device for these purposes.

This bill would make a technical, nonsubstantive change.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 109948.1 of the Health and Safety Code is amended to read:
- 109948.1. (a) "Home medical device services" means the 4 delivery, installation, maintenance, replacement of, or instruction
- in the use of, home medical devices used by a sick or disabled
- individual to allow the individual to be maintained in a residence.
- (b) "Home medical device" means a device intended for use
- 8 in a home care setting including, but not limited to, all of the
- following:

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- 1 (1) Oxygen delivery systems and prefilled cylinders.
- 2 (2) Ventilators.

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- 3 (3) Continuous Positive Airway Pressure devices (CPAP).
- 4 (4) Respiratory disease management devices.
- 5 (5) Hospital beds and commodes.
- 6 (6) Electronic and computer driven wheelchairs and seating 7 systems.
 - (7) Apnea monitors.
 - (8) Low air loss continuous pressure management devices.
- 10 (9) Transcutaneous Electrical Nerve Stimulator (TENS) units.
 - (10) Prescription devices.
- 12 (11) Disposable medical supplies including, but not limited 13 to, incontinence supplies as defined in Section 14125.1 of the 14 Welfare and Institutions Code.
 - (12) In vitro diagnostic tests.
 - (13) Any other similar device as defined in regulations adopted by the department.
 - (c) The term "home medical device" does not include any of the following:
 - (1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual's residence.
 - (2) Prosthetics and orthotics.
 - (3) Automated *or automatic* external defibrillators (AEDs).
- 28 (4) Devices provided through a physician's office incident to a physician's service.
 - (5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.
- 33 (6) Enteral and parenteral devices provided by a licensed 34 pharmacist.